

# Apheresis Horizon Scanning Report

Current demand on UK apheresis units and how this will  
change over the next 2 years

## Executive Summary

### Introduction

Clinical apheresis units are critical for the collection of starting materials required for many Advanced Therapy Medicinal Products' (ATMPs) manufacture. Current horizon scanning activities covering ATMPs often miss the impact on critical services like apheresis.

This report demonstrates the current demand on the UK's apheresis services, using Scotland as an exemplar region, and how this will change with the adoption of new licensed ATMPs captured in existing NHS England (NHSE) ATMP horizon scanning. All clinical trials requiring apheresis collection will create further additional demand.

### Methods

The project utilised an apheresis service survey developed by the Cell and Gene Therapy Catapult (CGT Catapult), the Advanced Therapy Treatment Centres Network (ATTC), the Scottish National Blood Transfusion Service (SNBTS) and NHSE's ATMP horizon scanning data to provide the basis of an analysis.

The survey conducted January – March 2023, provides information on Scottish apheresis units capacity and capabilities. The responders also reflected on how apheresis services have changed and their experiences of increasing capacity and capability. The horizon scanning data for licensed ATMPs provided by NHSE, redacted where appropriate to protect any commercial sensitivities, was collected in February 2023.

The data sources were extrapolated to cover the whole of the UK and analysed to quantify the change to demand for apheresis services caused by new ATMPs.

### Conclusion

The data shows that NHS apheresis services are currently operating close to or at full capacity. UK apheresis units will need to perform an additional 5,646 procedures per year to meet the needs of new ATMPs. This represents a 25% increase in demand for apheresis procedures. It is important to note that this project did not account for clinical trial ATMPs, which would represent an additional increase in demand for apheresis services.

In particular, the demand for Peripheral Blood Mononuclear Cell (PBMC) collections is expected to increase dramatically with 5,603 procedures per year required. To date demand for PBMC collections has been lower than other cell types. The change expected represents a ten-fold increase in demand for PBMC collections.

The fact that NHS apheresis services are currently operating at capacity, and the demand for these services is expected to increase over the next 2 years, represents a significant risk to the service and barrier to the adoption of ATMPs.

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## Introduction

The success of many Advanced Therapy Medicinal Products (ATMP) relies upon support services such as apheresis. Apheresis units are critical for the collection of cellular starting materials required for many ATMPs manufacture.

Current horizon scanning activities covering ATMPs focus heavily on the impact on services downstream of the medicinal product and often miss impact on critical upstream services like apheresis.

This report presents the findings from a horizon scanning exercise examining the current demand on apheresis units and how this will change in response to new licensed ATMPs coming online. All clinical trials requiring apheresis collection will create further additional demand. The information and analysis provided within this report will improve NHS readiness for changes in demand, ultimately enabling the treatment of patients on the greater scale expected.

## Methods

The project was developed by the Cell and Gene Therapy Catapult (CGT Catapult, the Advanced Therapy Treatment Centre (ATTC) Network in partnership with the Scottish National Blood Transfusion Service (SNBTS) and NHS England (NHSE). Due to the difficulty obtaining data for the UK as a whole, and in particular England, Scotland was used as an exemplar and then the overall UK demand was extrapolated from the Scottish data set. The project also only accounts for the adoption of licensed ATMPs and their effect on apheresis, clinical trial ATiMPs were not included. Data on the current and future demand for apheresis came from two main sources:

### 1. Apheresis Service Survey

The survey was developed, disseminated and results collated in partnership with CGT Catapult, ATTC Network and SNBTS.

### 2. NHSE ATMP Horizon Scanning Data

Horizon scanning data showing expected new licensed ATMPs, was shared by NHSE for use in the project. The data was redacted by NHSE before being shared to protect any commercial sensitivities.

The analysis of the findings presented in this report was conducted by CGT Catapult.

## Results

### Apheresis Service Survey

The apheresis survey was conducted across January – March 2023. The survey was sent to all apheresis units within Scotland, as an exemplar, to measure the capacity and capability of apheresis services. The apheresis units that completed the survey are:

- Aberdeen & Northeast of Scotland Transfusion Centre (**A&NSTC**)
- The Beatson West of Scotland Cancer Centre, Glasgow (**WOSC**)
- Clinical Apheresis Unit, Royal Infirmary Edinburgh (**CAU-RIE**)

The survey gathered information across two main areas;

1. **Service Capacity** – Focusing on the numbers of staff, beds and equipment available to perform procedures.
2. **Service Capability** – Focusing on the types of procedures performed, staff competencies and what services can be provided.

### *Apheresis Service Provision*

The apheresis service provision, across the sites contacted, is detailed in [Table 1](#) and [Table 2](#). Two of the three sites surveyed provide paediatric apheresis services i.e. The Beaton West of Scotland Cancer Care, Glasgow (WOSCC) and Clinical Apheresis Unit, Royal Infirmary Edinburgh (CAU-RIE) whilst all sites have adult services.

*Table 1. Apheresis Service Provision Profile of Surveyed Sites*

	<b>WOSCC, Glasgow</b>	<b>CAU-RIE, Edinburgh</b>	<b>A&amp;NSTC, Aberdeen</b>
<b>Serves Adults</b>	✓	✓	✓
<b>Serves Paediatrics</b>	✓	✓	x
<b>Respondent Role</b>	Senior Charge Nurse	Senior Charge Nurse	Consultant

Within the survey, sites were asked to provide the details of the specific apheresis procedures they perform, results of which can be found in [Table 2](#).

Notably, A&NSTC also provides a therapeutic venesection service. This was different to the remaining sites surveyed and represented 210 procedures performed. The therapeutic venesection service does not impact the facility's capacity to perform starting material collections for ATMPs, hence this has been removed from the analysis.

*Table 2. Apheresis Procedures Offered at Surveyed Sites*

<b>Apheresis Procedures Provided</b>	<b>WOSCC, Glasgow</b>	<b>CAU-RIE, Edinburgh</b>	<b>A&amp;NSTC, Aberdeen</b>
<b>Extracorporeal Photopheresis (ECP)</b>	✓	✓	x
<b>Peripheral Blood Stem Cell Collection</b>	✓	✓	✓
<b>Therapeutic Plasma Exchange</b>	✓	✓	✓
<b>Low Density Lipid Removal</b>	x	x	x
<b>Lymphocyte Collection</b>	✓	✓	✓
<b>Red Cell Exchange</b>	✓	✓	✓
<b>Blood Component Transfusion</b>	x	x	x
<b>Platelet Depletion</b>	✓	✓	✓
<b>White Cell Depletion</b>	✓	✓	✓
<b>CAR-T Cell Therapy</b>	✓	✓	x

### *Apheresis Service Capacity*

Survey responders were asked to reflect on the numbers of staff, beds and equipment available at their site. They were also asked how these numbers have changed over the preceding 2 years and how easy it is to increase capacity at their site to meet demand.

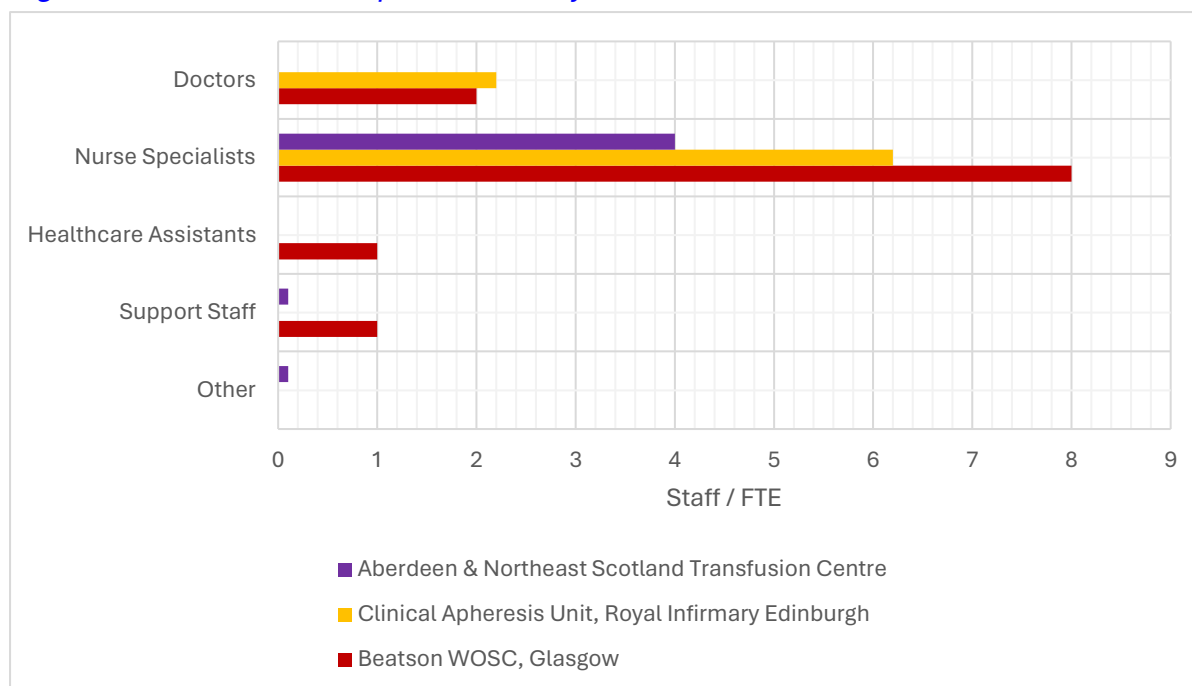
#### *Job Roles for Apheresis Delivery*

Survey responders were invited to report on the number of staff at their sites ([Figure 1](#)). Sites were also asked how this has changed over the past 2 years and if there are any expected changes to staffing in the future.

The predominant job role delivering apheresis services was nurse specialist. For the remaining job roles, included in the survey, there was a variable picture across the sites.

Many of the sites utilised fractional posts within the support staff and healthcare assistant job roles. (Figure 1).

Figure 1. Number of Staff per site surveyed



### Staff Changes in the Next 3-5 Years

Survey respondents were asked to predicted changes in staffing over the next 3-5 years. This timeframe was chosen to enable responders to forecast staff changes far enough in the future to exclude short term changes, such as staff replacement, promotion, back fill and parental leave. Such shorter-term changes were captured elsewhere in the survey.

Across the sites, WOSCC predicted at least 1 support staff member would be added and commented “No planned changes at present but business case being progressed for additional secretarial support.”

The CAU-RIE predicted 1 healthcare assistant would be replaced, although they responded that healthcare assistants did not administer apheresis, this information was included to give a picture of staff turnover across the service, not only in staff performing apheresis. They commented, “Unsure of any changes coming.”

### Apheresis Beds and Operating Machines

WOSCC has 5 beds and more than 10 apheresis machines in operation. There had been no change in the number of apheresis machines over the past 2 years and no current plans to purchase more. Perceived barriers to increasing capacity included:

1. Stem cell lab processing availability
2. Unpredictability of workload
3. Increased regulatory burden

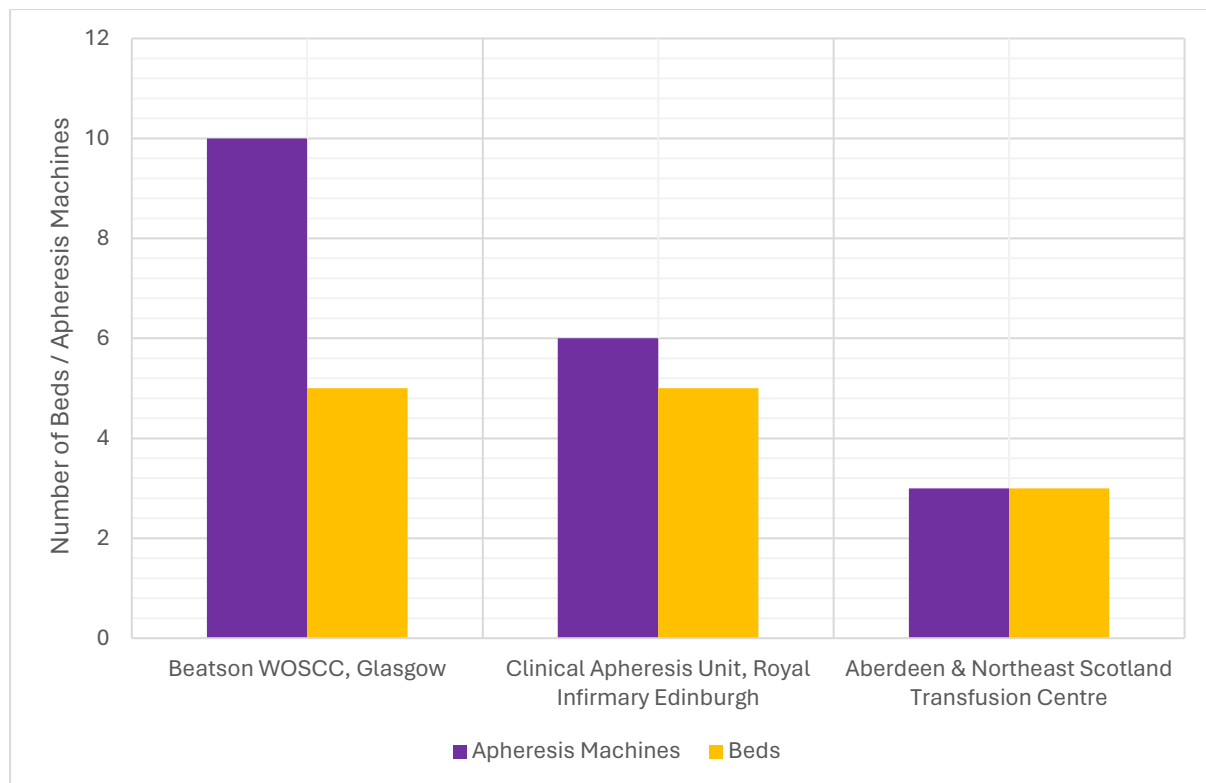
CAU-RIE has 5 beds and 6 apheresis machines in operation. There had been no change in the number of apheresis machines over the past 2 years and possibly plans to purchase more. Perceived barriers to increasing capacity included:

1. Existing space may limit service expansion
2. Staff numbers are inadequate
3. Expense contributes to budgetary challenges

A&NSTC has 3 beds and 3 apheresis machines in operation. There had been no change in the number of apheresis machines over the past 2 years but there were plans to increase the number in the future. The perceived barriers to increasing capacity include:

1. Funding
2. Staff recruitment & retention
3. *No third barrier identified*

*Figure 2 Facility bed numbers and operating apheresis machines.*

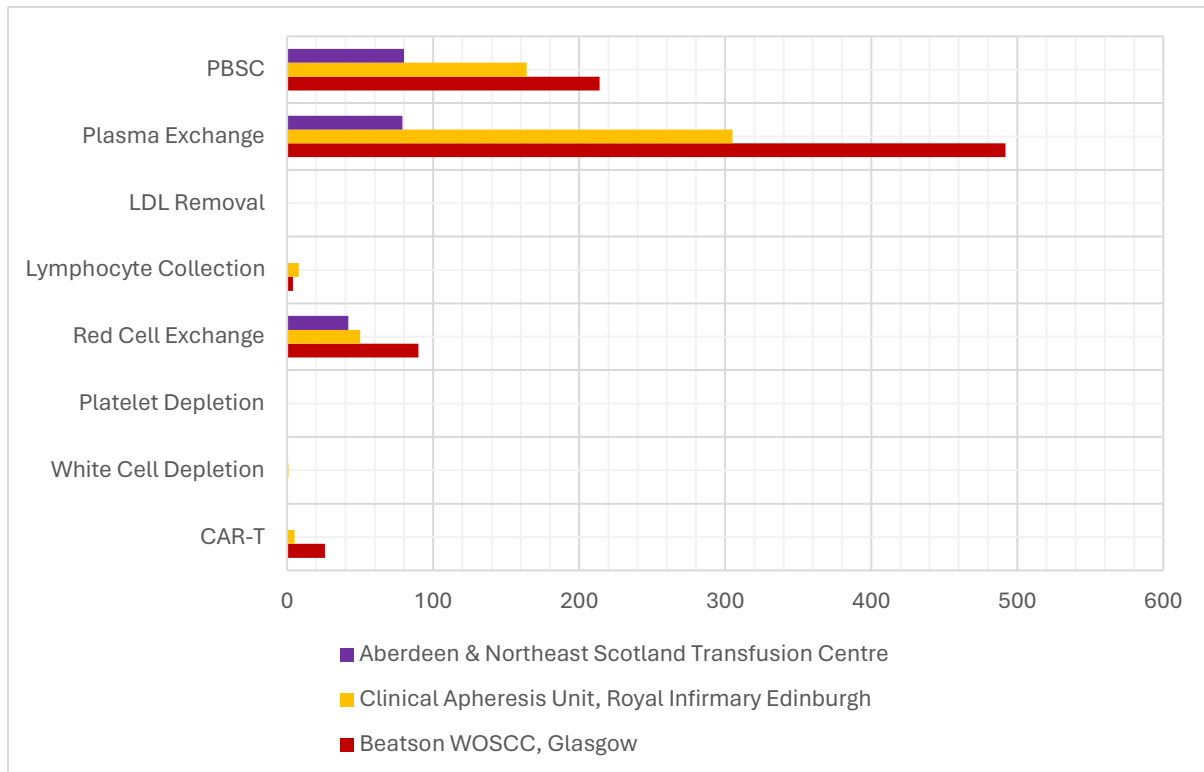


### *Apheresis Operating Capacity*

Ten types of apheresis procedures were performed by the sites surveyed (Figure 3) and the responses indicate that these sites are working at capacity.

WOSCC and CAU-RIE saw a 10% and 30% increase in demand respectively whilst none was reported by A&NSTC.

Figure 3. Procedures performed by sites in 2022



The number of procedures performed by sites is presented in [Figure 3](#).

Sites were also asked to reflect on how they found the process of increasing capacity on a scale of 1 (very easy) to 10 (very difficult) and to think of the last time their service hired a new member of staff or purchased a new piece of equipment in terms of hiring and training the new member of staff or setting up and using the new equipment. Except A&NSTC, the sites rated increasing capacity as neither difficult nor easy (n5) when asked about their experience of increasing or improving capacity. A&NSTC reported that it was moderately difficult (n3) to increase capacity.

All site respondents indicated the introduction of ATMPs clinical trials impacted apheresis capacity moderately or less. WOSCC noted a minor impact, CAU-RIE stated a moderate impact. A&NSTC indicated no impact on apheresis capacity.

All site respondents indicated the extent to which the introduction of licensed ATMP services impacted on apheresis capacity as moderate. This question was not applicable for A&NSTC as it did not offer ATMP related apheresis services.

## Apheresis Service Capability

Survey responders were asked to reflect on the types of apheresis procedures they perform, numbers and type of staff competent to deliver them and the ability to deliver a 7-day service. They were also asked how to reflect on changes to this over the preceding 2 years and how easy it is to add capabilities to their site.

### Apheresis Service Staff Competence

The number of staff competent to perform a procedure did not always correlate with the type of procedures performed at specific sites ([Table 2](#); [Figure 1](#)). The service would not function without the apheresis non-administration support staff.

The reason for the apparent discrepancy is that the survey did not make a distinction between staff who delivered and staff involved in other aspects of the service.



In Scotland, nurses are competent at performing all apheresis procedures including ATMP starting material collection. The service is doctor-led but the clinicians involved have a number of local and national responsibilities. The service is best described as nurse delivered and therefore one of the primary influences on apheresis service capacity and capability is number of competent nurses.

#### *7-day Apheresis Service Offering*

Scottish sites offer a 7 day apheresis service, but the procedures delivered out of hours are not ATMP starting material collections.

WOSCC commented “*We operate a weekend service for emergency procedures only at present (mostly emergency plasma exchange or red cell exchange). We don't currently perform PBSC collection or lymphocyte collection at weekends. This is mostly because there is no Stem Cell Lab service available at the weekend. We are also constrained to some extent by the number of apheresis nurses available.*”

CAU-RIE noted “*No - we currently have an on call 24/7 service for plasma exchange, Red cell exchange and white cell depletion but at moment don't have staff to expand others.*”

A&NSTC stated “*It would be too expensive to run a 24/7 service for our population size*”

#### *Apheresis Procedures to be Adopted in the Next 3-5 Years*

Respondents indicated that no further apheresis procedures were currently being planned to be performed at their sites in the next 3–5 years compared to those in 2022. The only notable exception was the expansion of the CAR-T collection and allogenic donor collection services at the CAU-RIE.

#### *Embedding New Capabilities at Sites*

On a scale of 1 (very difficult) to 10 (very easy) site respondents indicated their experience of embedding new capabilities at the site was variable (Figure 4). Respondents were asked to think of the last time their service had to collect a new cell lineage or collect to new specifications, and the practicalities of implementing the change.

WOSCC scored 6, interpreted here as moderately easy. The top three barriers this respondent perceived to improving capabilities at the site were:

1. Excessive regulatory burden
2. Inconsistencies between different ATMP manufacturers in approach to apheresis
3. Increasingly limited financial resource

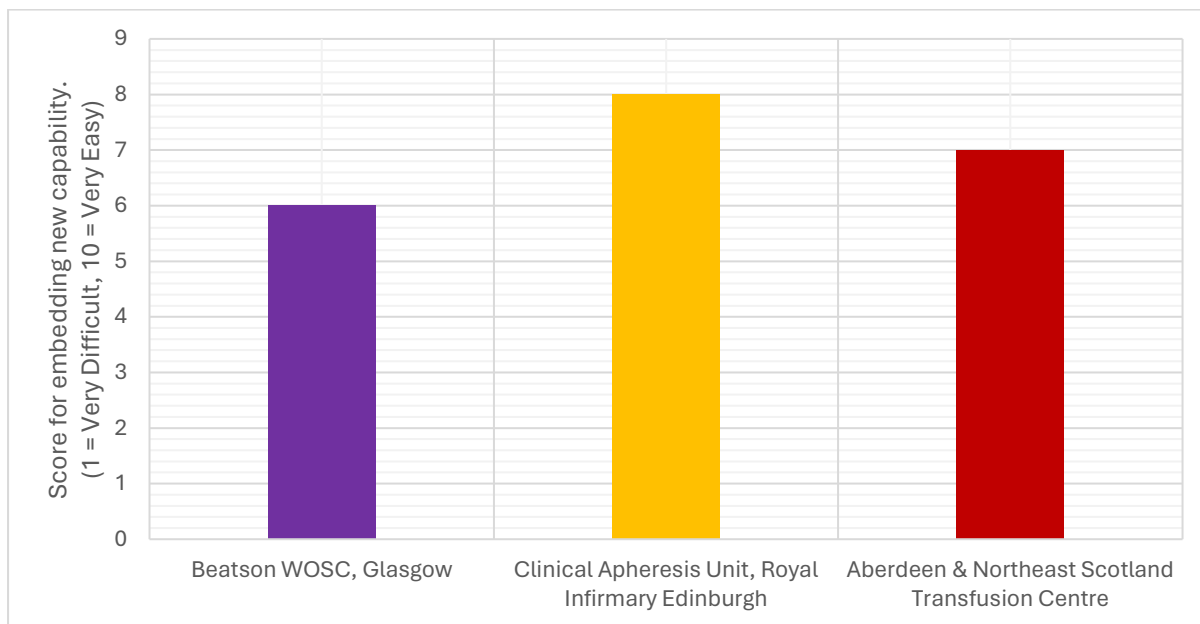
CAU-RIE scored 8, interpreted here as being easy. The major barrier this respondent perceived to improving capabilities at their site was staffing.

1. Existing space may limit service expansion
2. Staff numbers are inadequate
3. Expense contributes to budgetary challenges

A&NSTC scored 7, moderately easy. The major barriers this responder perceived were:

1. Funding
2. Staff recruitment & retention
3. *Did not submit a third*

Figure 4. Sites experience of embedding new capabilities



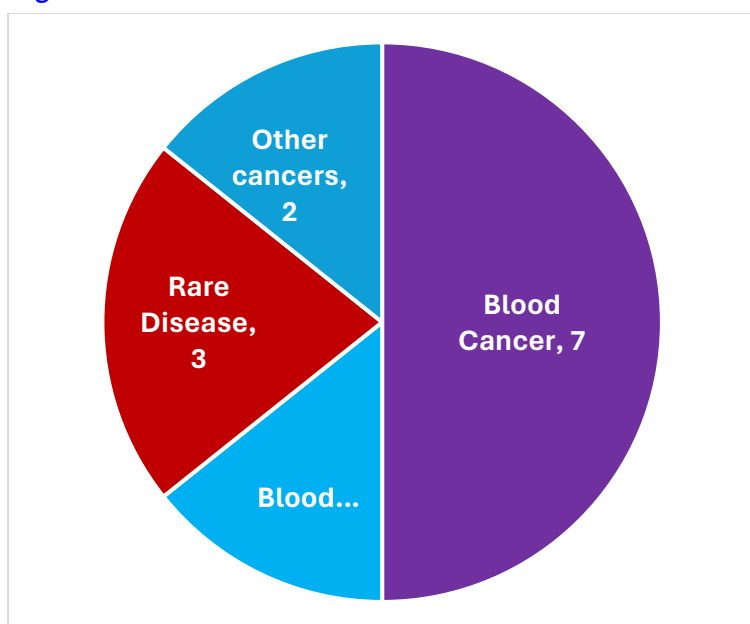
### Advanced Therapy Medicinal Product (ATMP) Horizon Scanning Data

NHSE provided CGT Catapult non-commercially sensitive data from its ongoing licensed ATMP horizon scanning work and the figures below represent the consolidated view of a snapshot (February 2023) of this data. It is only representative of the approved ATMPs expected to be adopted in England, clinical trial ATiMPs were not included.

#### Scanning Overview

There are 14 new licensed ATMPs split across 4 broad indication areas that will impact UK apheresis units and patient numbers over the next 2 years (Figure 5, Table 3). All these ATMPs require a collection via apheresis of either Peripheral Blood Mononuclear Cells (PBMC) or Peripheral Blood Stem Cells (PBSC), with PBMC showing the greatest number of new patients.

Figure 5. ATMP numbers across 4 broad indications areas



### *Change in Patient Numbers*

The 14 ATMPs forecast result in a potential increase in patients presenting at English apheresis units of 4,316 – 5,167 per year for the next 2 years (Table 3). This data does not account for patients presenting within the devolved nations within the UK.

The data below is an estimation of the number of new patients and does not account for patients requiring multiple apheresis procedures per treatment.

*Table 3. The increase in patient numbers per year per starting material procurement type*

	New ATMPs (number)	New Patients (number)		Starting Materials			
				Peripheral Blood Mononuclear Cells		Peripheral Blood Stem Cells	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
<b>Blood Cancer</b>	7	4,050	4,094	4,050	4,094	0	0
<b>Blood Disorder</b>	2	20	45	0	0	20	45
<b>Other Cancer (Oncology)</b>	2	246	1,023	246	1,023	0	0
<b>Rare Disease</b>	3	0	5	0	0	2	5
<b>TOTAL</b>	14	4,316	5,167	4,296	5,117	22	50

Most new patients will require PBMC collections and will be within the Blood Cancer cohort. Much of the approximate 4,000 new patients are known to be myeloma patients to be treated with Chimeric Antigen T-cell Therapy (CAR-T). It has become clear, since the provision of the NHSE horizon scanning data, that there are supply issues for CAR-T for this patient group. This casts a higher degree of uncertainty on this data than there would have otherwise been.

The second most prevalent apheresis procedures will be within the Other Cancer cohort and again will be PBMC collections. However, there is a much greater range in the number of potential patients shown here in the data. This may represent a higher degree of uncertainty in the patient population.

PBSC collections in the Blood Disorders and Rare Disease cohorts represented the least number of new patients from the data.

## Analysis

The project's goal is to be able to draw meaningful conclusions on the current and future demand for apheresis services reflecting the increased number of licensed ATMPs being adopted in the UK.

It should be noted that the data sets acquired cover different geographies and relate to different populations. The apheresis service survey interrogated capacity and capability for Scotland, but not for England, Northern Ireland or Wales; whereas the NHSE ATMP horizon scanning data captures new ATMPs and patient numbers for England only i.e. not the devolved nations. Therefore each data source was extrapolated to quantify the impact of the new ATMPs on the whole UK apheresis service, with further detailed analysis of PBMC and PBSC collections. None of the data sets used in this project capture clinical trial ATiMPs or their effect on demand for apheresis services. See Assumptions and Constraints for more detail.

## Whole of the UK

The total number of all additional apheresis procedures calculated for the whole of the UK is 5,646 (Table 4). This is a median figure from the NHSE ATMP horizon scanning data extrapolated to include all four nations of the UK.

The calculated current total UK capacity for apheresis procedures per year is 22,363, the projected requirement would be to provide 28,007 procedures per year. This results in a projected UK shortfall of 5,646 apheresis procedures per year.

*Table 4. Impact on Apheresis – UK*

	Patient No. for the UK
<b>Number of New Apheresis Procedures Required (Median) / year</b>	5,646
<b>New Total Apheresis Procedures Required (Existing + Horizon) / year</b>	28,007
<b>Calculated UK Total Apheresis Capacity / year</b>	22,363
<b>Shortfall / Surplus</b>	<b>-5,646</b>

## Peripheral Blood Mononuclear Cell Collections

The greatest increase in apheresis demand and shortfall in apheresis capacity is linked to PBMC collections (Table 5) whilst the current capacity to perform these collections is one of the lowest.

*Table 5. Impact on PBMC Collections - UK*

	Patient No. for the UK
<b>Number of New PBMC Collection Procedures Required (Median) / year</b>	5,603
<b>New Total PBMC Collection Procedures Required (Existing + Horizon) / year</b>	6,140
<b>Calculated UK Total PBMC Collection Capacity / year</b>	538
<b>Shortfall / Surplus</b>	<b>-5,603</b>

The projected demand for PBMC collections will increase ten-fold over the next 2 years, representing a shortfall of approximately 5,600 PBMC procedures based on current capacity.

## Peripheral Blood Stem Cell Collections

The projections of PBSC collections are more positive, Table 6 shows that the increase in demand for PBSC collections is relatively low (n43). PBSC collections are one of the most highly performed apheresis procedures, and this has factored in the calculation of the PBSC collection capacity for the UK.

The data shows that the new PBSC collections required in response to the adoption of new ATMPs could reasonably be performed using existing capacity.

Table 6. Impact on PBSC Collections – UK

	Patient No. for the UK
Number of new procedures required (Median) / year	43
New Total Procedures required (Existing + Horizon) / year	5,768
PBSC Capacity / year	5,725
Shortfall / Surplus	-43

## Conclusion

This report presents a picture of apheresis capacity and how this will change due to the adoption of new licensed ATMPs. Although the original intention was to gather data from both England and Scotland, the approach was revised to use Scotland-wide data when some of the English sites did not respond to the survey. The data gathered has been extrapolated to cover the whole of the UK and aims to meet the original aims of the project.

It is key to recognise that all the apheresis units surveyed are operating at capacity and that demand for their services has already increased by 10%-20% over the last 2 years. The sites reflected that funding staff and infrastructure were major barriers to increasing capacity and capability. Appropriately resourcing apheresis units, including the adequate compensation for ATMP starting material collections is critical.

The ATMP horizon scanning data showed a potential 25% increase in demand for apheresis procedures relating to the adoption of licensed ATMPs (i.e. an additional 5,646 procedures). The biggest increase is seen in the requirement for PBMC collections, a ten-fold increase in demand is shown in the projections. PBMC collections have historically been performed in small numbers and projected increase will be a considerable undertaking for the NHS. It is important to note that this project only accounts for licensed ATMPs, clinical trial ATMPs would further increase the demand for apheresis services.

In conclusion, new ATMPs on the horizon for adoption in the UK requires the NHS to increase capacity to meet the new demand. The projections show the NHS is considerably under capacity particularly for PBMC collections. The UK's apheresis service need to markedly increase its capacity to meet future demand, the community reports that this will require apheresis units to be more effectively compensated to cover the costs for the procedures they perform.

## Assumptions & Constraints

Apheresis capacity data (annual number of procedures performed plus current capacity for additional procedures) was available for Scotland. This data was extrapolated to represent the UK-wide capacity by adjusting for the difference in population size between Scotland and the UK, assuming that the number of procedures performed is proportional to the population size that each centre covers. ATMP horizon scanning data (annual number of expected procedures) was available for licensed products in England. This data was extrapolated for the UK by adjusting for the difference in population size between England and the UK, assuming that ATMP access across the UK is proportional to population size. Therefore, any differences in apheresis capacity or ATMP access across the devolved nations is a limitation of the validity of the results presented here.